Remarks

Claims 1-26 and 42-55 are pending. Claims 1, 3, 5, 8, 11-14, 16, 18, 19, 23, 43-47, 49, and 50-52 have been amended. Claims 9, 17, 20, 22, 25, 42, and 48 have been canceled. New claim 56 has been added.

Amendments to Objected-To Claims

Claims 3-7, 11, 13, 14, 25, 26, 49, and 52[1] were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form. Claims 3, 5, 11, 14, 49, and 52 have been amended into independent form. Claim 25 has been canceled and rewritten as new, independent claim 56. These amendments should moot the objection of claims 3-7, 11, 14, 25, 49, and 52.

Amendments to Rejected Claims

Claim 1 has been amended to specify that the microchip device is *packaged for implantation* into a patient and that the reservoirs contain a *release system comprising drug molecules*. Support for the amendment is found at least at original claims 9, 12, 17, and 22 and at page 23, lines 16-20; page 5, lines 2-4; and pages 7-9.

Claims 8, 10, 12, and 13 have been amended to comport with the change to claim 1 and the cancellation of claim 9.

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[1] The Office Action indicated claim 51 was both rejected and objected to and failed to indicate the status of claim 52. In a telephone conversation with the undersigned on July 23, 2003, the Examiner clarified that the Office Action was in error: claim 52 was objected to and claim 51 was rejected.

Claim 16 has been amended to specify that the method is for delivery of *drug* molecules *into a patient* by providing the device at a site *in the patient* and that that the reservoirs contain a *release system comprising drug molecules*. Support for the amendment is found at least at original claims 9, 12, 17, and 22 and at page 23, lines 16-20; page 5, lines 2-4; and pages 7-9.

Claims 18, 19, and 23 have been amended to comport with the change to claim 16 and cancellation of claims 17, 20, and 22. Claims 43-47, 50, and 51 have been amended to comport with the change to claim 1 and cancellation of claim 42.

Rejection Under 35 U.S.C. § 103

Claims 1, 2, 8-10, 12, 15-24, 42-48, 50, 51, and 53-55 were rejected under 35 U.S.C. § 103(a) as obvious over WO 97/34697. For convenience, U.S. Patent No. 6,114,658 to Roth et al. (hereinafter "Roth") shall be referenced herein and considered an English-language equivalent of the cited German-language PCT publication. The rejection is respectfully traversed if applied to the claims as amended.

The Patent Office has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *See* In re Fine, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). "It can satisfy this burden only by showing some *objective teaching* in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." Id. As detailed below, no *prima facie* case of obviousness has been established in the present application.

Roth

Roth discloses that it is known to be desirable to encapsulate sensitive materials. Roth lists the following as general classes of sensitive materials: chemical indicator materials,

catalysts, and pharmaceuticals (col. 1, lines 9-10). Roth indicates that conventional methods for encapsulating such sensitive materials include "encapsulation of the substance in a glass bulb, plastic foils or similar packings." (col. 1, lines 20-22). The "encapsulating device" of Roth is directed to the encapsulation and exposure of a sensor.

In particular, Roth is focused exclusively on devices and systems for ***in vitro*** analytical devices and systems. This evident by the discussion in Roth of DE 3919042 and other German patent documents at column 1. For example, DE 3919042 is directed to "**structures** [] **used for evaluation** and documentation in biotechnology, genetic engineering, cell or immune research, **or for other medical**, agriculture or environmental **research**." (See attached English-language abstract of DE 3919042). Roth fails to disclose or suggest that its "encapsulating device" can or should be packaged for implantation in a patient or adapted for drug delivery.

Furthermore, Roth fails to disclose or suggest using its device for the controlled **release** of any material of interest, as it discloses only *exposure* of an encapsulated material.

Roth Fails to Provide Any Motivation for *In Vivo* Drug Delivery

Claims for an invention are not *prima facie* obvious if the primary references do not suggest all elements of the claimed invention and the prior art does not suggest the modifications that would bring the primary references into conformity with the application claims. In re Fritch, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992); see In re Geiger, 815 F.2d 686 (Fed. Cir. 1987) (Prior art must provide one of ordinary skill in the art with the motivation to make the proposed modifications needed to arrive at the claimed invention). While Roth discloses that "pharmaceuticals" are sensitive materials that have been encapsulated in glass bulbs, plastic foils

or similar packings, that disclosure does not remotely suggest an *implantable* device for drug delivery. On the contrary, Roth suggests only *in vitro* type packaging and analysis.

Roth does not remotely disclose or suggest an **implantable medical device**. Nothing in the prior art remotely suggests to one of ordinary skill in the art that the device in Roth could or should be modified or packaged for implantation into a patient or for drug delivery. The rejection seems to rely on the term "pharmaceutical." Roth, however, at best can be construed as describing *in vitro* **testing** of possible pharmaceutical compounds; it cannot be viewed as teaching anything about delivery of a drug into a patient. Nothing in Roth provides any motivation to modify its device to achieve an implantable device for drug delivery as claimed by the present applicants.

The Office Action Fails to Provide Clear and Particular Showing Required to Meet the PTO's Burden for Establishing Obviousness

The Office Action has not provided the required *clear and particular* showing that Roth suggests the desirability, and thus the obviousness, of making the claimed combination of elements. The Court of Appeals for the Federal Circuit has explained that to sustain an obviousness rejection "**particular findings** must be made as to the **reason** the skilled artisan, with no knowledge of the claimed invention, **would have selected these components for combination in the manner claimed**." In re Kotzab, 217 F.3d 1365, 1371 (Fed. Cir. 2000). The Examiner alleges that "it is well known to implant such a drug-carrying microsystem into a patient. This vague rationale is totally unsupported by Roth or any other evidence. It cannot support a *prima facie* case of obviousness.

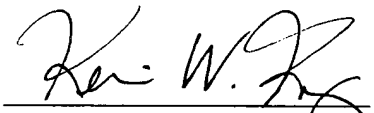
The Office Action's rejection is improperly based on hindsight reconstruction or the use of references that are not prior art. At best, the rejection is based on improper hindsight reconstruction coupled with mere speculation as to why one skilled in the art today *might* modify the encapsulating device disclosed in Roth.

Conclusions

For the reasons detailed above, the Office Action does not provide sufficient evidence to show that one of ordinary skill in the art at the time of applicants' invention, would have modified Roth into conformity with applicants' claims. Therefore, no proper *prima facie* case of obviousness has been established. The rejection is thus improper and should be withdrawn.

Allowance of claims 1-8, 10-16, 18, 19, 21, 23, 24, 26, 43-47, and 49-56 is therefore respectfully solicited.

Respectfully submitted,



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